

*Patent*

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Appendix 1

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## Back to the Drawing Board

By Lawrence Camel

November 1, 2005

### Nabi Biopharmaceuticals (NABI<sup>1</sup>)

**Share price as of Monday's close: \$12.85**

**Share price now: \$3.63**

**Change: -71.8%**

**Volume: 55.2 million shares, daily average 813,200 shares**

**Last time this low: July 23, 2002**

**52-week high: \$16.00**

**52-week low: \$10.23**

**Forward P/E before news: n/a**

**Forward P/E after news: n/a**

**THE SELLING WAS infectious on Tuesday.**

Shares of **Nabi Biopharmaceuticals (NABI<sup>2</sup>)** plummeted 72% to a three-year low of \$3.63 after the biotechnology company announced that its experimental vaccine against potentially deadly staph infections flunked a critical late-stage clinical trial. As a result of the failure of StaphVax to deter infections in kidney patients undergoing dialysis, the company halted development of the drug, which some analysts said had blockbuster potential. More than 55 million shares changed hands Tuesday, compared to the stock's average daily volume of 813,000.

"Basically, most people investing in [Nabi] were investing in StaphVax," says Kate Winkler, an analyst at San Francisco brokerage Global Crown Capital. "And if that's you, then there's no reason to be in it any longer. This was the thing that was going to catapult it into the next level. Now it will not be catapulted, but instead remain a small-cap biotech." (Winkler doesn't own shares of Nabi Biopharmaceuticals; Global Crown Capital doesn't have an investment-banking relationship with the company.)

Early Tuesday, the Rockville, Md., company announced that the jewel of its drug pipeline, StaphVax, failed to meet the primary goal of its latest Phase III trial. Commonly known as staph, *Staphylococcus aureus* are a group of bacteria that can lead to a variety of serious infections, especially in those with suppressed immune systems. Each year about 500,000 patients in U.S. hospitals contract staph infections. Nabi's trial of 3,600 kidney patients on dialysis found that even though StaphVax was effective in generating a high quantity of specific antibodies, it was no more effective than a placebo in reducing staph infections.

"The results are certainly a tremendous surprise and disappointment for all of us," said Thomas McLain, Nabi's chief executive, during Tuesday's conference call. "All indications, including the previous Phase III trial, supported we had a viable product with the potential to prevent a major cause of health-care-associated infections. This was a well-designed and well-executed Phase III clinical trial, but the study did not meet our objectives to confirm that StaphVax prevented blood stream infections in end-stage renal disease patients." The company plans to further evaluate the results and release its findings in a few months.

In addition to terminating the trial, Nabi halted further development of StaphVax and withdrew its application to sell the vaccine in the European Union. Nabi also ended development of Altastaph, an experimental staph vaccine similar to StaphVax. Management said it would stop all spending on these two vaccines immediately and redirect funds toward other drugs in its pipeline.

"Clearly there was big potential here, but now it's zero," says Kevin DeGeeter, an analyst at Dawson James Securities, an investment bank in Boca Raton, Fla. DeGeeter had anticipated approval for StaphVax in late 2006 and had projected potential annual revenue of \$750 million by 2011. "Is the platform the problem or is it specific to StaphVax, and is the pipeline still viable? Those are the important questions, and we don't know the

answers." (DeGeeter doesn't own shares of Nabi Biopharmaceuticals; Dawson James Securities doesn't have an investment-banking relationship with the company.)

With the staph drugs shelved indefinitely, Nabi's best hopes for approval now include a smoking vaccine<sup>3</sup> and a hepatitis C treatment. The company recently was awarded a \$4.1 million grant from the National Institutes of Health to develop NicVax, a vaccine designed to treat nicotine addiction and prevent smoking relapse. A current Phase II trial should be completed by the end of this year. Civacir is being developed for the prevention of hepatitis C after liver transplant. The NIH has already funded and conducted a Phase VII clinical trial of the hepatitis C drug.

Unlike other early-stage biotechs, Nabi does have three products on the market. PhosLo controls elevated phosphorus levels in patients with end-stage renal failure, Nabi-HB is a passive immunization that offers short-term protection following exposure to the hepatitis B virus, and Aloprim reduces levels of serum uric acid in patients with leukemia, lymphoma and solid-tumor malignancies who are receiving cancer therapy.

But none of them are big sellers. For the third quarter, Nabi reported a net loss of \$16.1 million on sales of \$30.8 million. A year earlier the red ink added up to \$10.9 million on sales of \$43.8 million. As of Sept. 30, the company had \$137 million in cash. According to Global Crown's Winkler, Nabi's net cash flow for the trailing 12 months was negative \$63 million, with an estimated cash burn for 2005 of \$75 million.

"The financial implications of all of these changes are being evaluated," said Nabi CEO McLain. "but we have no specific information that we are able to share with you today." The company has enough cash, he said, to continue working on the drugs in its pipeline.

**Quote:**

"This is a really important setback. This drug is essentially dead," says Dawson James's DeGeeter. "Everyone is really in the dark today. What happened wasn't on anybody's radar screen. The company doesn't understand why the study failed but it did, and that is the important thing."

**Links in this article:**

<sup>1</sup><http://www.smartmoney.com/eqsnaps/index.cfm?story=snapshot&symbol=NABI>

<sup>2</sup><http://www.smartmoney.com/cfscripts/Director.cfm?searchString=NABI>

<sup>3</sup><http://www.smartmoney.com/onedaywonder/index.cfm?story=20040928>

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